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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,869	05/04/2001	David J. Anderson	CALTE.004C1	1088

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/09/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/849,869

Applicant(s)
Anderson et al.

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 14, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1646

Claims 1 to 86 are pending in the instant application.

Claims 1 to 17, 24 to 39 and 84 to 86 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

The restriction requirement of Paper Number 17 is hereby vacated. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I to LII. Claims 1, 3, and 5 to 14, only in so far as they relate to an isolated nucleic acid molecule encoding any one of the 52 different sequences recited therein, classified in class 435, subclass 69.1. Invention I, for example, includes claims 1, 3, 5, 7 to 14, only in so far as they relate to an isolated nucleic acid molecule encoding SEQ ID NO :2. Invention LII includes claims 1, 3, 5, 7 to 14, only in so far as they relate to an isolated nucleic acid molecule encoding SEQ ID NO :109.

LIII to LV. Claims 2 and 4 to 14, only in so far as they relate to an isolated nucleic acid molecule comprising any one of the 3 different sequences recited therein, classified in class 435, subclass 69.1.

Art Unit: 1646

LVI to CVII. Claims 15, 16, 18 to 20, 24, 38 and 39, only in so far as they relate to an isolated polypeptide comprising any one of the 52 different sequences recited in claim 16, classified in class 530, subclass 350.

CVIII to CX. Claims 15, 17, 21 to 23, 25, 38 and 39, only in so far as they relate to an isolated polypeptide comprising any one of the 3 different sequences recited in claim 17, classified in class 530, subclass 350.

CXI to CLXII. Claims 26 to 31 and 38 to 42, only in so far as they relate to an antibody which binds to a polypeptide comprising any one of the 52 different sequences recited in claim 16, classified in class 530, subclass 388.22.

CLXIII to CLXV. Claims 32 to 39, only in so far as they relate to an antibody which binds to a polypeptide comprising any one of the 3 different sequences recited in claim 17, classified in class 530, subclass 388.22.

CLXVI to CCXVII. Claims 43 to 56 and 62 to 64, only in so far as they relate to a binding assay employing an isolated polypeptide comprising any one of the 52 different sequences recited in claim 16, classified in class 436, subclass 501.

CCXVIII to CCLXIX. Claims 57 to 61 and 66 to 83, only in so far as they relate to a binding assay employing a recombinant cell expressing a heterologous polypeptide comprising any one of the 52 different sequences recited in claim 16, classified in class 435, subclass 7.21.

Art Unit: 1646

CCLXX to CCCXXI. Claim 65, only in so far as it relates to a process of identifying a compound which effects the expression level of a chimeric protein comprising any one of the 52 different sequences recited in claim 16, classified in class 435, subclass 69.7.

CCCXXII to CCCLXXIII. Claim 84, only in so far as it relates to a transgenic animal comprising a recombinant nucleic acid encoding any one of the 52 different sequences recited in claim 16, classified in class 800, subclass 2.

CCCLXXIV to CDXXV. Claims 85 and 86, only in so far as they relate to a method of treatment by administering to a mammal an "agent" of unspecified constitution which increases the level of expression of a polypeptide comprising any one of the 52 different sequences recited in claim 16, classification undeterminable.

The inventions are distinct, each from the other because:

The fifty five different nucleic acids of inventions I to LV, the fifty five different polypeptides of inventions LVI to CX, the fifty five different antibodies of inventions CXI to CLXV, the fifty two different animals of inventions CCCXXII to CCCLXXIII, and the fifty two different "agents" of employed in the methods of inventions CCCLXXIV to CDXXV are one hundred sixty nine different chemical compounds each of which can be made and used without the others. Lack of unity is shown by the fact that these one hundred sixty nine different compounds

Art Unit: 1646

do not share a common utility which is based upon a common special technical feature or structural lacking from the prior art.

Each of the isolated polypeptides that are inventions LVI to CVII are related to each of the binding assays of inventions CLXVI to CCXVII as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the polypeptides, as claimed, can be employed as an immunogen for the production of antibodies thereto, which process is materially different from the claimed binding assays.

Each of the host cells comprising the nucleic acid molecules of inventions I to are related to each of the binding assays of inventions CCXVIII to CCLXIX as well as each of the expression assays of inventions CCLXX to CCCXXI as a product and two materially different processes of use, respectively. They are shown to be distinct because the binding assays of inventions CCXVIII to CCLXIX and the expression assays of inventions CCLXX to CCCXXI achieve different objectives by employing different method steps.

Because these inventions are distinct for the reasons given above and the search required for any one of the different sequences recited in the claims would not be required for the examination of any one of the other recited sequences, restriction for examination purposes as indicated is proper.

Art Unit: 1646

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800